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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,136	08/18/2006	Anthony John Ujhazy	3869/049 US	1415
23440 7590 01/15/2009 GOTTLIEB RACKMAN & REISMAN PC 270 MADISON AVENUE 8TH FLOOR NEW YORK, NY 10016-0601				
EXAMINER BEHRINGER, LUTHER G				
ART UNIT		PAPER NUMBER		
3766				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/598,136

Applicant(s)

UJHAZY ET AL.

Examiner

LUTHER G. BEHRINGER

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-15 and 32-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-15 and 32-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This office action is in response to the communication received on 11/25/2008 concerning application no. 10/598136 filed on 08/18/2006.

Response to Arguments

2. Applicant's arguments with respect to claim(s) 1, 3 – 15 and 32 – 34 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claim(s) 1, 3 – 6 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Testermann et al. (US 5,540,733, herein Testermann)** in view of **Ottenhoff et al. (US 6,251,126, herein Ottenhoff)** in view of **Pitts (US 2002/0049479)**.

With regard to **claim(s) 1 and 34**, Testermann discloses a method of treating sleep disordered breathing comprising the steps of delivering treatment so as to prevent airway collapse if said patient is asleep (Col. 6, ll. 19 – 23), determining the presence of an obstruction in said patient's airway, and if an obstruction is present increasing said treatment until said obstruction is no longer present, wherein said treatment comprises applying electrical stimulation of afferent nerves (Abstract, Col. 8, ll. 29 – 53), said presence of an obstruction is determined by sensing a change in transthoracic impedance (Col. 18, ll. 18 – 21). Testermann fails to disclose determining the likelihood

of a patient being asleep, and said patient's sleep state is determined based upon the time of day and the patient's postural state.

However, Ottenhoff teaches determining the likelihood of a patient being asleep (Col. 5, Lines 32 – 36).

5. A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of determining the likelihood of a patient being asleep to achieve optimal stimulation for therapy purposes. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Testermann to include determining the likelihood of a patient being asleep as taught by Ottenhoff, since doing so would optimize therapy delivery and as a result minimize extraneous therapy delivery thereby conserving battery power.

Testermann in view of Ottenhoff discloses where said patient's sleep state is determined based upon the patient's postural state (Testermann: Col. 15, ll. 9 – 24), but fails to disclose determining that information based on the time of day and. However, Pitts teaches utilizing the time of day as criteria for stimulation delivery (Abstract).

6. A person of ordinary skill in the art at the time of the invention would have recognized the obvious advantages of combining the art recognized equivalents of stimulating based on time of day as disclosed by Pitts and posture sensing as disclosed by Testermann to provide a more appropriate stimulation to a patient when most required.

Regarding **claim 3**, Testermann in view of Ottenhoff in view of Pitts discloses wherein the site of electrical stimulation is within or adjacent to the genioglossus muscle (Pitts: Abstract).

With regard to **claim 4**, Testermann in view of Ottenhoff in view of Pitts discloses wherein the site of electrical stimulation is in the vicinity of the hypoglossal motor nucleus or excitatory afferent nerve pathways leading to this structure (Pitts: Abstract).

Regarding **claim 5**, Testermann in view of Ottenhoff in view of Pitts discloses wherein the electrical stimulation comprises trains of electrical pulses (Testermann: Figs. 10 – 17; Col. 8, line 54 – Col. 9, line 30).

With regard to **claim 6**, Testermann in view of Ottenhoff in view of Pitts fails to disclose wherein the train length is approximately 10-30 pulses.

7. Testermann in view of Ottenhoff in view of Pitts discloses the claimed invention except for the specified length of the pulse train. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize a pulse train length of 10 – 30 pulses, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding **claim 13**, Testermann in view of Ottenhoff in view of Pitts discloses wherein stimulation is repeated in accordance with the detected state of the airway (Testermann: Abstract).

8. Claim(s) 7 – 12, 15 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Testermann et al. (US 5,540,733, herein Testermann)** in view of **Ottenhoff et al. (US 6,251,126, herein Ottenhoff)** in view of **Pitts (US 2002/0049479)** in view of **Bowers (US 5,207,230)**.

Regarding **claim(s) 7 and 15**, Testermann in view of Ottenhoff in view of Pitts discloses all of the limitation of claims 7 and 15 as disclosed in claim 1 above, with the exception of utilizing mechanical stimulation to accomplish stimulation of afferent nerves.

However, Bowers teaches a method of treating sleep disordered breathing comprising the step of mechanical stimulation of nerves to increase muscle tone of upper airway muscles (Col. 3, Lines 20 – 23).

9. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Testermann in view of Ottenhoff in view of Pitts with the teachings of Bowers to provide an alternative mechanical stimulation of nerves that more efficiently delivers apneic therapy.

With regard to **claim 8**, Testermann in view of Ottenhoff in view of Pitts in view of Bowers discloses wherein mechanical stimulation is performed by a piezo electric mechanical element (Bowers: Col. 3, Lines 20 – 23) implanted at a site in the vicinity of the upper airway (Pitts: Abstract).

Regarding **claim 9**, Testermann in view of Ottenhoff in view of Pitts in view of Bowers discloses wherein the piezo-electric mechanical element is implanted within or adjacent to the base of the genioglossus muscle (Pitts: Abstract).

With regard to **claim(s) 10 and 11**, Testermann in view of Ottenhoff in view of Pitts in view of Bowers discloses wherein the mechanical stimulation is periodic, on the order of several seconds of vibration (Bowers: Col. 10, Lines 25 – 30; Pitts: [0029]).

Regarding **claim 12**, Testermann in view of Ottenhoff in view of Pitts in view of Bowers discloses wherein the mechanical vibration occurs at frequencies in the range of 10-50 Hz (Pitts: [0029]).

With regard to **claim 32**, Testermann in view of Ottenhoff in view of Pitts in view of Bowers discloses wherein stimulation is repeated in accordance with the detected state of the airway (Testermann: Abstract).

10. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Testermann et al. (US 5,540,733, herein Testermann)** in view of **Ottenhoff et al. (US 6,251,126, herein Ottenhoff)** in view of **Pitts (US 2002/0049479)** in view of **Park et al. (US 6,904,320, herein Park)**.

With regard to **claim 14**, Testermann in view of Ottenhoff in view of Pitts fails to disclose wherein stimulation is carried out in accordance with a model of Cheyne-Stokes Respiration.

However, Park teaches wherein stimulation is carried out in accordance with a model of Cheyne-Stokes Respiration (Col. 7, Lines 41 – 44).

11. A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of stimulating according to a model of Cheyne-Stokes Respiration to achieve airway patency. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Testermann in view

of Ottenhoff in view of Pitts to include stimulation for Cheyne-Stokes Respiration, a type of sleep apnea, as taught by Park, since treating for both obstructive sleep apnea and central sleep apnea in a single device could simplify therapy choices for practitioners.

12. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Testermann et al. (US 5,540,733, herein Testermann)** in view of **Ottenhoff et al. (US 6,251,126, herein Ottenhoff)** in view of **Pitts (US 2002/0049479)** in view of **Bowers (US 5,207,230)** in view of **Park et al. (US 6,904,320, herein Park)**.

Regarding **claim 33**, Testermann in view of Ottenhoff in view of Pitts in view of Bowers fails to disclose wherein stimulation is carried out in accordance with a model of Cheyne-Stokes Respiration.

However, Park teaches wherein stimulation is carried out in accordance with a model of Cheyne-Stokes Respiration (Col. 7, Lines 41 – 44).

A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of stimulating according to a model of Cheyne-Stokes Respiration to achieve airway patency. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Testermann in view of Ottenhoff in view of Pitts to include stimulation for Cheyne-Stokes Respiration, a type of sleep apnea, as taught by Park, since treating for both obstructive sleep apnea and central sleep apnea in a single device could simplify therapy choices for practitioners.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LUTHER G. BEHRINGER whose telephone number is (571)270-3868. The examiner can normally be reached on Mon - Thurs 8:00 - 5:30; 2nd Friday 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

/Luther G Behringer/
Examiner, Art Unit 3766